

REMARKS

The pending Office Action addresses and rejects claims 1-26 and 29-63. Applicants respectfully request reconsideration and allowance based on the remarks submitted herewith.

At the outset, Applicants thank Examiner Cumberledge for the courtesy of a telephone interview on August 21, 2008 with the undersigned attorney and attorney Lisa Adams for Applicants. Although no agreement was reached, Applicants appreciate the Examiner clarifying his position with respect to U.S. Patent No. 5,209,753 of Biedermann et al.

Rejections Pursuant to 35 U.S.C. § 103(a)

U.S. Patent No. 5,209,753 of Biedermann et al. in view of U.S. Patent No. 5,122,132 of Bremer

The Examiner rejects claims 1-7, 12, 13, 15, 16-22, 29-35, 40-46, and 48-55 pursuant to 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,209,753 of Biedermann et al. (“Biedermann”) in view of U.S. Patent No. 5,122,132 of Bremer (“Bremer”). The Examiner argues that Biedermann discloses an apparatus for attaching tissue to bone as claimed except for the distal tip member being of a harder material than a proximal main member. The Examiner relies on Bremer to remedy the deficiencies of Biedermann. Applicants disagree.

Claims 1-7, 12, 13, 15, and 16-22

Claim 1 is directed to an apparatus for attaching tissue to bone that includes an expandable body having a proximal main member and a distal tip member, an expander pin that expands the expandable body laterally when the expander pin is driven into the expandable body, and a tissue attachment member *formed on a shaft of the expander pin*. When the expander pin is driven into the expandable body, the expandable body is attached to the bone and the tissue attachment member secures tissue to the apparatus. As recited in claim 1, the distal tip member has a threaded recess and the proximal main member *has* a distally extending threaded recess and *a distally extending threaded projection* threadably interengageable with the distal tip member recess.

Biedermann is directed to a bone screw that is used as a pedicle screw. (See Col. 1, lines 4-6.) The bone screw (1) includes an intermediate threaded portion (2) that can be expanded by first

engaging a shaft of an expander pin (16) located proximal of the intermediate expandable threaded portion (2) with an expander part (12) that is located distal of the intermediate expandable threaded portion (2), and then unscrewing the expander pin (16) to move the expander part (12) in a proximal direction to expand the intermediate threaded portion (2). (See Col. 2, lines 19-29 and 34-45.) The Examiner asserts that the expander part (12) forms the claimed distal tip member, the expandable threaded portion (2) forms the claimed proximal main member, and the shaft of the expander pin (16) forms the claimed expander pin. While the Examiner admits Biedermann fails to teach the distal tip member (12) being formed of a harder material than the proximal main member (2), the Examiner has overlooked several additional deficiencies of Biedermann.

Biedermann fails to teach or even suggest an apparatus for attaching tissue to bone that includes a proximal main member having a distally extending threaded projection. Rather, Biedermann teaches *an expander pin (16) having* a distally extending threaded projection (18). In the most recent Office Action, the Examiner argues that even though the threaded projection (18) is on the expander pin (16) of Biedermann, the threaded projection (18) can still be considered part of the intermediate expandable portion (2) because the threaded projection (18) *is connected to the intermediate expandable portion (2)* when the device is used. (Emphasis added.) The Examiner's interpretation, however, fails to acknowledge the fact that the claim specifically requires that the proximal main member of the expandable body *has* a distally extending threaded projection. The Examiner's interpretation fails to give any meaning to the word "having."

While "having" can have a variety of meanings, a person having ordinary skill in the art interpreting the meaning of a claim would understand the word "having" to mean "to consist of (as all one's elements or constituent parts): contain, include," as in "*have* a subordinate part" or "*the car has* a self-starter." (Webster's Third International Dictionary.¹) A person having ordinary skill in the art could also interpret the word "having" as used in the context of a claim to mean "to be

¹ Webster's Third New International Dictionary is the dictionary most often cited by the Federal Circuit in claim construction matters. It is cited 25% of the time in all claim construction cases by the Federal Circuit, and 36% of the time when the Federal Circuit seeks a general purpose English dictionary. See Miller, Joseph Scott and Hilsenteger, James A., "The Proven Key: Roles and Rules for Dictionaries in the Patent Office and the Courts" (October 5, 2004).

marked, distinguished, or characterized by (as an attribute, quality, position, or a distinctive biographical fact),” as in “the cloth *has* a silky texture.” (*Id.*) These definitions, and particularly the examples, from Webster’s Third International Dictionary are clearly appropriate and applicable to Applicants’ intentions in claiming “said proximal main member having a distally extending threaded projection.” Just as Webster’s Third International Dictionary interprets “have” as a way to describe constituent parts or distinguishing characteristics, Applicants use the word “have” to describe constituent parts and distinguishing characteristics of the proximal main member of the expandable body, namely a distally extending threaded projection. An expandable body that does not include such a distally extending threaded projection cannot be considered to be the equivalent of the claimed expandable body.

Based on both the most recent Office Action and a discussion between the undersigned attorney, attorney Lisa Adams, and the Examiner, the Examiner would be satisfied if Applicants amended the claims to state that the distally extending threaded projection is monolithic with respect to the expandable body. Such a requirement, however, is inappropriate because it ignores the meaning of the word “having.” “Having” means to consist of or be marked, distinguished, or characterized by particular features. Based on the Examiner’s interpretation, any claim that recites a particular component “having” a particular feature or further component disposed thereon would need to further include the word monolithic. Thus, based on the Examiner’s interpretation, a claim to “a table having a top and six legs” would read on a table having a top, four legs, and a person with two legs sitting at the table since the person and table are put together. The only way to distinguish over a four-legged table with a person would be to recite “a table that includes a top and six legs monolithically formed with the top.” The Examiner’s interpretation would render hundreds of thousands of patents invalid because they fail to recite that particular components are “monolithic” with respect to each other. The Examiner’s interpretation ignores the meaning of the word “having” and is plainly absurd.

Further, in light of the fact that only the expander pin (16) of Biedermann includes a distally extending threaded projection (18), it would be inappropriate to consider the expander pin (16) of

the Biedermann apparatus (1) as an expandable body comprising a proximal main member. The expander pin (16) is not expandable, and thus cannot be considered to be part of the intermediate expandable portion (2). Further, if by coupling the expander pin (16) to the intermediate expandable portion (2) the expander pin (16) can be considered to be part of the intermediate expandable portion (2), then Biedermann lacks any teaching of an expander pin. The expander pin (16) *cannot* be both an expander pin and a proximal main member of an expandable body. Claim 1 recites two separate components, each having particular characteristics; such recitations *cannot* be ignored.

At least because Biedermann fails to teach or even suggest an expandable body comprising *a proximal main member* having a distally extending threaded projection, and instead teaches *an expander pin* having a distally extending threaded projection, the rejection cannot be maintained.

Biedermann also fails to teach or even suggest an apparatus for attaching tissue to bone that includes a tissue attachment member formed on a shaft *of the expander pin*. Even though Biedermann is a bone screw (1) that is particularly suited for use as a pedicle screw and thus would not be used by a person having ordinary skill in the art to attach tissue to bone, the Examiner alleges that the head (3) of the bone screw (1) is the equivalent of Applicants' tissue attachment member (210). Even if the head (3) of the bone screw (1) could possibly be used to attach tissue to bone, the head (3) of the bone screw (1) is formed *on the intermediate expandable threaded portion (2) (i.e., the proximal main member)*, not *the shaft of the expander pin (16)* as required by claim 1. In fact, a person having ordinary skill in the art would never form a tissue attachment member on the shaft of the expander pin (16) of Biedermann because the expander pin (16) is removed from the bone screw (1) once the implantation is complete. This is vastly different from the claimed apparatus, which maintains the expander pin (200), and thus the tissue attachment member (210), as part of the apparatus even after the implantation is complete.

In the most recent Office Action, the Examiner does not contest Applicants' arguments that the alleged tissue attachment member (3) of Biedermann is not formed *on the shaft of the expander pin (16)* of Biedermann as required by claim 1. Rather, the Examiner argues that the language "a

tissue attachment formed on said shaft” is a product-by-process recitation. The Examiner states that the device of Biedermann appears to be substantially identical to the claimed device, and that although the device of Biedermann is produced by a different process (i.e., the alleged tissue attachment member is attached on the expandable body and not the expander pin when the device is assembled), asserts that it is the burden of Applicants to provide evidence of an unobvious difference between the two.

The recitation “a tissue attachment member formed on said shaft” is not a product-by-process claim. The Examiner appears to be arguing that use of the word “formed” is indicative of a product-by-process claim, but such an interpretation is incorrect. Claim 1 clearly recites a product and in no way recites a process. Use of the word “formed” conventionally describes the location of the tissue attachment member with respect to the shaft of the expander pin. It clearly and concisely defines a structure in which the shaft of the expander pin includes a tissue attachment member. Applicants do not recite a process by which the tissue attachment member is formed on the expander pin. Rather, Applicants only claim that the tissue attachment member is formed, i.e., located, on the shaft of the expander pin. At least because no steps or processes are recited, this cannot be considered a product-by-process claim.

Further, even if the recitation “a tissue attachment member formed on said shaft” can be considered to be a product-by-process claim, there are clear, unobvious differences between the claimed apparatus for attaching tissue to bone and the apparatus of Biedermann, and thus the rejection cannot be maintained. If the Examiner does properly make out a case of *prima facie* obviousness for a product-by-process claim, Applicants can show an unobvious difference between the claimed product and the prior art product. (See MPEP § 2113.) When assessing the patentability of product-by-process claims over the prior art, *the structure implied* by the process steps should be considered. (*Id.*) (Emphasis added.) As recited by claim 1, a tissue attachment member is formed on said shaft. Even if another process, such as coupling the expander pin (16) to the intermediate expandable portion (2) of the apparatus (1) of Biedermann is performed, it does not change the structure of the expander pin (16). In Biedermann, the alleged tissue attachment member

(3) *is always* located on the intermediate expandable portion (2) and can never be part of the expander pin (16). Accordingly, the *structure* of Biedermann, even in view of an alleged process, can never be the same as the structure recited in claim 1. Further, a person having ordinary skill in the art would never change the apparatus (1) of Biedermann to form the alleged tissue attachment member (3) on the expander pin (16) because such an apparatus would not be operable. If the alleged tissue attachment member (3) were placed on the expander pin (16), the apparatus (1) would not be capable of holding tissue at least because the expander pin (16) is removed from the apparatus (1).

Accordingly, even if claim 1 is construed to be a product-by-process claim, the apparatus of Biedermann remains structurally different from the claimed apparatus and thus fails to teach or even suggest an apparatus for attaching tissue to bone that includes a tissue attachment member *formed on the shaft of the expander pin*.

Bremer, which the Examiner relies upon to teach an apparatus where a distal portion is made from a harder material than a proximal main portion, does not remedy the deficiencies of Biedermann, at least because Bremer does not include any expandable body or expander pin. In fact, Bremer is not even configured to expand.

Claim 1, as well as claims 2-7, 12, 13, 15, and 16-22 which depend therefrom, therefore represents allowable subject matter.

Claims 29-35, 40-46, and 48-55

Claim 29 is directed to an apparatus for attaching tissue to bone that includes an expandable body, an expander pin that expands the expandable body laterally when the expander pin is driven into the expandable body, and a tissue attachment member formed on a shaft of the expander pin. When the expander pin is driven into the expandable body, the expandable body is attached to the bone and the tissue attachment member secures tissue to the apparatus.

The only component of Biedermann that expands the intermediate expandable portion (2) is the expander part (12). The expander pin (16) is used to move the expander part (12), but it does not expand the intermediate expandable portion (2). Nevertheless, even if the expander pin (16) is considered to be a component that expands the intermediate expandable portion (2), neither it nor the expander part (12) includes anything that can be considered to be a tissue attachment member. Accordingly, as explained in more detail above, Biedermann fails to teach or even suggest an apparatus for attaching tissue to bone that includes a tissue attachment member formed on a shaft of an expander pin.

Further, Biedermann also fails to teach or even suggest an apparatus in which, *when* the expander pin (16) is driven into the intermediate expandable portion (2), the intermediate expandable portion (2) is attached to the bone *and* the alleged tissue attachment member (3) secures the tissue to the apparatus (1). Movement of the shaft of the expander pin (16), either driving it into or removing it from the proximal main member (2), fails to secure any tissue to the apparatus (1). To the extent that it can be argued that the alleged tissue attachment member (3) secures tissue to the apparatus, it certainly does not occur when the expander pin (16) is driven into the intermediate expandable portion (2). Bremer fails to remedy any of the deficiencies of Biedermann, as previously explained.

Claim 29, as well as claims 30-35, 40-46, and 48-55, therefore represents allowable subject matter.

U.S. Patent No. 5,209,753 of Biedermann et al. in view of U.S. Patent No. 5,122,132 of Bremer further in view of any one of U.S. Patent No. 5,370,662 of Stone et al., U.S. Patent No. 5,948,002 of Bonutti, U.S. Patent No. 5,725,529 of Nicholson, and U.S. Patent No. 5,078,818 of Moll et al.

The Examiner makes a number of further obviousness rejections pursuant to 35 U.S.C. § 103(a), relying on Biedermann, Bremer, and one of a number of different references. More particularly, the Examiner further relies on U.S. Patent No. 5,370,662 of Stone et al. to reject claims 8-10 and 36-38, U.S. Patent No. 5,948,002 of Bonutti to reject claims 11 and 39, U.S. Patent No.

5,725,529 of Nicholson to reject claims 14 and 47, and U.S. Patent No. 5,078,818 of Moll et al. to reject claims 23-26 and 56-59. None of the references cited by the Examiner remedy the deficiencies of Biedermann. Accordingly, at least because claims 8-11, 14, 23-26, 36-39, 47, and 56-59 depend from allowable base claims, each claim also represents allowable subject matter.


Conclusion

All pending claims are believed to be in condition for allowance. If the Examiner believes that an interview would facilitate the resolution of any outstanding issues, he is kindly requested to contact the undersigned.

Date: September 25, 2008

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Respectfully submitted,



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